COMMISSION GUIDELINE ON THE FORMAT AND CONTENT OF APPLICATIONS FOR PAEDIATRIC INVESTIGATION PLANS (ARTICLE 10 OF REGULATION (EC) NO 1901/2006) - CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION – December 2013

COMMENTS FROM : Dinah Duarte, Hugo Tavares, Helena Fonseca (INFARMED, I.P.)

GENERAL COMMENTS

We welcome the publication of this update to the Guideline on the format and content of applications for PIPs that includes a simplification of the procedure to submit the PIP and clarification of the rules about what kind of information should be submitted. The clarification regarding indication and condition (and its implication on multiple PIps) is welcomed and the improvement regarding the clear definition and agreement in the compliance check measures (as well as the interim check) are very important to have a correct implementation of the Regulation.

We agree with the proposed format and content of applications for agreement on or modification of a paediatric investigation plan and requests for waivers or deferrals, and have no further comments (Page 21).

We agree with the proposed operation of the compliance check and with the compliance statement (Page 23).

Regarding the criteria for assessing the significance of studies started before and completed after the Pediatric Regulation, this allow the possibility of recognizing (from studies planned and conducted before the entry into force of the Pediatric Regulation) the clinical relevance of the results generated in the pediatric population. Through these criteria presented in page 25 of the document, we could potentially:

a) ensure that only the best clinical evidence is used to decide on the relevance of pediatric use (benefit assessment / positive risk).
b) potentiate valid scientific data in pediatric subgroups traditionally most difficult to recruit for clinical trials (eg neonatal period, prematurity and rare diseases).
c) safeguard the best interests of the children by not submitting to unnecessary duplication of clinical trials.